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Docket No.: 101896-0234  
(DEP5100CIP)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Tushar Patel et al.

Application No.: 10/777,019

Confirmation No.: 2233

Filed: February 11, 2004

Art Unit: 3733

For: TISSUE RETRACTOR AND GUIDE DEVICE

Examiner: D. C. Comstock

**COMMENTS FOR PRE-APPEAL BRIEF REVIEW**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

These comments are being filed concurrently with a Notice of Appeal and a Pre-Appeal Brief Request for Review.

Claims 1-6, 8, 10-18, and 27-55 are pending and stand rejected.

***Claim Rejections Pursuant to 35 U.S.C. §102***

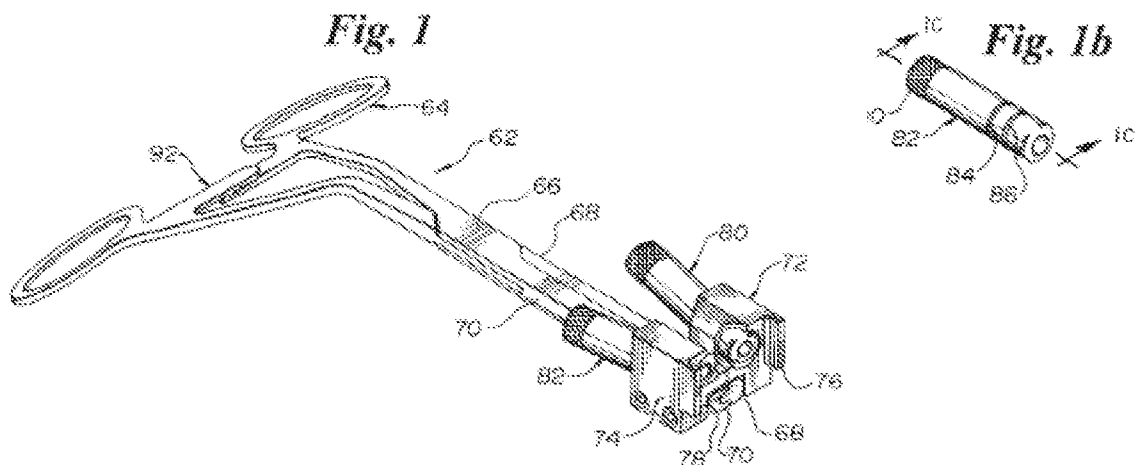
Claims 1-6, 8, 10-14, 16, 17, 27, 29-48 and 51-53 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,676,666 of Oxland et al. ("Oxland"). Applicant respectfully disagrees.

***Claims 1-6, 8, 10-14, 16, 17, 27, and 29-30***

The Examiner argues that Oxland discloses a guide member having a cut-out portion extending between first and second pathways of the guide member and that the cut-out portion provides visual access to a spinal implant. Specifically, the Examiner states on pages 2-3 of the Office Action dated February 8, 2008 that the pathways of Oxland's guide members 80, 82 "are directed toward each other

along a converging path. As such, a component of each opening faces toward the other end and can be considered the 'cut-out' portions in communication with each other." This is incorrect.

First, there is no cut-out portion in Oxland. As clearly shown in Figs. 1 and 1b of Oxland, which are reproduced below, the guide members 80, 82 are cylindrical tubes. The only possible openings in the guide members 80, 82 that face each other are the open distal ends of the tubes. Open ends are not cut-outs. The guide members 80, 82 simply have faces of cylindrical tubes at their distal ends. Nothing is cut out. Under any reasonable interpretation, a person having ordinary skill in the art would not consider open faces of tubes, or amorphous space beyond them, as a cut-out portion.



Second, there is no cut-portion in Oxland that extends between the two pathways of the tubular guide members 80, 82. The guide members 80, 82 are distinct cylindrical tubes having distinct cylindrical pathways. Nothing extends between the guide members' pathways. Even if the openings in the distal faces of the guide members 80, 82 are somehow considered a cut-out portion, there is still no cut-out portion extending between the guide members' openings. Only amorphous open space with no definition exists between the guide members' faces, and amorphous open space between two open tubular faces is not and cannot reasonably be considered a cut-out portion extending between two pathways. For instance, all of the open space in a room surrounding a pile of drinking straws dropped and scattered on a floor cannot reasonably be considered a cut-out portion between the open faces of all the drinking straws. Otherwise, open space between any two or more tubular structures would be a cut-out portion, thereby rendering the claim language meaningless.

Third, even if the openings in the distal faces of the guide members 80, 82 are considered a cut-out portion, Oxland's cut-out portion does not and cannot provide visual access to a spinal implant. Claim 1 requires that the guide member is adapted to be positioned in relation to a spinal implant such that each of the pathways in the guide member is aligned with at least one corresponding bore formed in the spinal implant to guide a tool through the bore *and* that the cut-out portion provide visual access to the spinal implant. As shown in Figs. 4 and 5 of Oxland, the guide members 80, 82 are adapted to be aligned with holes 34 in a spinal implant 12. Thus, if the open ends of the guide members 80, 82 are considered to be the cut-out portions as asserted by the Examiner, the open ends will not provide visual access to the implant 12 because they will be aligned with the holes 34. Thus, the open ends will only allow visual access to open space seen through the implant 12 and not to the implant 12 itself. Furthermore, when tools are inserted through the pathways of the guide members 80, 82, the cut-out portion identified by the Examiner would not provide visual access to the spinal implant 12 because the tools would extend through the open faces of the guide members 80, 82. Moreover, the presence of the tools would eliminate the cut-out portion of Oxland altogether because the open faces of the guide members 80, 82 would no longer be open.

Accordingly, independent claim 1 distinguishes over Oxland. Claims 2-6, 8, 10-14, 16, 17, 27, 29-48 and 51-53 are allowable at least because they depend from claim 1.

#### Claims 31-36

At least for the reasons discussed above, Oxland does not disclose a cut-out portion and independent claim 31 therefore distinguishes over Oxland. Even if the openings in the distal faces of the guide members 80, 82 are considered a cut-out portion as argued by the Examiner, the cut-out portion is not formed in a front sidewall because the cut-out portion is not formed in anything. It is merely empty space along non-defined converging paths of the guide members' pathways. Moreover, the device in Oxland does not have a front sidewall, so the cut-out portion cannot be formed in a front sidewall. Accordingly, independent claim 31 distinguishes over Oxland. Claims 32-36 are allowable at least because they depend from claim 31.

#### Claims 37-39

At the outset, independent claim 37 distinguishes over Oxland at least because Oxland does not have a front sidewall, as required by claim 37.

Claim 37 further distinguishes over Oxland because Oxland fails to teach a cross member removably connected to two tissue retractor and guide devices. The Examiner asserts that the hinge of Oxland's device is a cross member as recited in independent claim 37, but that is incorrect. First, Oxland does not in any way teach or suggest connecting *two* tissue retractor and guide devices, so Oxland correspondingly does not disclose anything that could reasonably be considered a cross member connected to two tissue retractor and guide devices. Second, even if Oxland's hinge, a pivot joint 66, is considered a cross member connected to two tissue retractor and guide devices, the hinge is integrally formed with Oxland's device and is thus not removably connected to two tissue retractor and guide devices as required by claim 37. Oxland does not disclose a pivot pin or any other member that is separate from the device's arms 68, 70. The arms 68, 70 are merely formed such that they can pivot relative to each other.

Accordingly, independent claim 37 distinguishes over Oxland. Claims 38-39 are allowable at least because they depend from claim 37.

*Claims 40-48 and 51-53*

Independent claim 40 distinguishes over Oxland at least because Oxland does not disclose that at least a portion of the first and second pathways are in communication with one another, as required by claim 40. As discussed above, the guide members 80, 82 in Oxland are distinct cylindrical tubes having distinct cylindrical pathways. Nothing extends between the pathways except non-defined empty space. If the pathways are considered to be in communication through such empty space, independent claim 40 would lose its meaning because under that interpretation, openings on any faces of any tubes facing each other would be considered in communication. It is simply not reasonable to consider, for example, that a tube being held by a person standing outside in New York is in communication with a tube being held by a person standing outside in California because empty space in the sky exists between converging paths from open ends of the tubes. Accordingly, independent claim 40 distinguishes over Oxland. Claims 41-48 and 51-53 are allowable at least because they depend from claim 40.

***Rejections Pursuant to 35 U.S.C. §103***

*Claims 28, 54, and 55*

Claims 28, 54, and 55 are rejected pursuant to 35 U.S.C. §103(a) as being made obvious over Oxland. As explained above, Oxland does not teach or even suggest all of the elements of independent

claims 1 and 40. The Examiner's reliance on Official Notice is only directed to various dependent claim features. Therefore, claim 28, which ultimately depends from claim 1, and claims 54 and 55, which ultimately depend from claim 40, distinguish over Oxland and represent allowable subject matter.

*Claims 15, 18, 49, and 50*

Claims 15, 18, 49, and 50 are rejected pursuant to 35 U.S.C. §103(a) as being made obvious over Oxland in view of U.S. Patent No. 4,686,972 of Kurland ("Kurland"). As explained above, Oxland does not teach or even suggest all of the elements of independent claims 1 and 40. Kurland does not remedy the deficiencies of Oxland. Kurland is directed to a surgical femoral deflector and drilling guide and does not concern or even ever mention spinal implants or spinal fixation plates. Therefore, claims 15 and 18, which ultimately depend from claim 1, and claims 49 and 50, which ultimately depend from claim 40, distinguish over Oxland and Kurland, taken alone or combined, and represent allowable subject matter.

***Conclusion***

In view of the above remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested.

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Respectfully submitted,

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